

INFORMED CONSENT – EAR RECONSTRUCTION SURGERY

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INFORMED CONSENT – EAR RECONSTRUCTION SURGERY

INSTRUCTIONS

This is an informed-consent document which has been prepared to help inform you about ear reconstruction and or Otoplasty (ear enhancement) surgery, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Ear reconstruction with or without otoplasty is a surgical procedure to remove skin lesion and cartilage from either the inner or outer ear. This surgical procedure may be required to address defects of the ear that result from trauma, skin cancer, or other deformities. In some cases the opposite ear will need surgery to obtain symmetry or to match the diseased ear. On occasion, underlying soft tissue or support structures can be selectively removed or repositioned during reconstruction. The main goal of ear reconstruction is to restore ear shape, appearance, and function. Otoplasty can also be used to improve the aesthetic shape of the inner or outer ear. It can help improve hearing or match in patients with significantly deformed or prominent ears. Although it can add natural shape or ear creases to the deformed ear, it will not completely erase evidence of disease or deformity. Ear reconstruction may require more than one stage depending on the size of the defect or deformity. Your board certified plastic surgeon can discuss the reconstruction in detail during your clinical consultation.

Ear reconstruction is often required after the removal of an ear lesions or skin cancer. Ear lesions include all benign, pre-cancerous, and cancerous masses of the skin of the inner or outer ear. Skin screening is best performed by a dermatologist or primary care physician not a plastic surgeon. Your plastic surgeon may give you an opinion about a skin lesion but without a skin sample it is only an estimate. It is important to note that no physician can ever be absolutely sure of any eyelid lesion. Even a biopsy can be inaccurate at times. If an ear lesion is of concern then it should be sampled or removed. Based on the skin sample a plan may be devised for observation, local treatment, radiation, or full removal with or without a margin. Plastic surgeons often remove skin lesions that are large or in sensitive areas on the ear. After the lesion is removed then surgical reconstruction may be in order. These procedures may be done in the office or in the hospital setting. Plastic surgeons role in this area is primarily as a technician for removal and closure of the ear area that concern the patient or a referring physician.

Often when a skin cancer is found in a sensitive area such as the nose, face, or ears more advanced removal techniques may be in order. MOHS surgery is a technique where a specially trained dermatologist removes a skin lesion using advanced and detailed techniques. This technique can be over 99% effective in removing most types of skin cancer. After the lesion is removed the MOHS specialist may close smaller defects, but larger defects usually require the skills of a board certified Plastic Surgeon. Your surgeon will make the appropriate recommendations at the time of consultation.

Ear reconstruction with or without Otoplasty surgery is customized for every patient, depending on his or her particular needs. It can be performed alone involving upper, lower or both eyelid regions, or in conjunction with other surgical procedures of the eye, face, brow, or nose. In some patients, who have larger or prominent ears, consideration for ear shaping (Otoplasty at the time of ear reconstruction may be recommended. Ear reconstruction surgery cannot completely restore your normal appearance. It can however, diminish the deformity, improve symmetry, and restore part or all external ear function.

Ear surgery requires a commitment from the patient and all those involved in the patient's care. Patients who have had a great deal of sun exposure often have multiple areas that must be addressed over time. It is often best to focus on a limited number of areas with each visit. Ear lesion care involves prevention as well as treatment. It is important to wear appropriate skin cover and skin screens particularly in the summer months. Each patient must participate in their own skin health by informing their physician of areas of concern or change. In summary, ear surgery with reconstruction is a team effort that often involves the combined skills of the patient, primary care physician, dermatologist, ENT, and plastic surgeon.

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ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the ear deformity. Improvement of skin laxness, support structures (cartilage) and skin redundancy may be accomplished by other treatments or surgery such as a tissue flaps or staged procedures when indicated. Other forms of ear surgery may be needed should you have disorders affecting the function or shape of the ear such as drooping or prominent ears that result from problems from structural support or birth defects. Minor ear scars or defects may be improved through chemical skin-peels, laser resurfacing, or other skin treatments. Risks and potential complications are associated with alternative surgical forms of treatment.

RISKS OF EAR RECONSTRUCTION SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand all possible consequences of ear reconstruction with or without otoplasty surgery.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Bleeding may occur under the skin or internally around the eyeball. Intraoperative blood transfusions may be required. Should post-operative bleeding occur, it may require emergency treatment, surgery, or blood transfusion. Do not take any aspirin or anti-inflammatory medications for ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hypertension (high blood pressure) that is not under good medical control may cause bleeding during or after surgery. Accumulations of blood under the eyelids may delay healing and cause scarring. Hematoma can occur at any time following injury. If blood transfusions are needed to treat blood loss, there is a risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

Infection- Infection is unusual after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

Hearing Problems- Patient will require a regimen of ear products including ear drops that are intended to protect the ear after surgery. These products often result in pain or decreased hearing during use. Patients may be unable to wear hearing aids for several weeks after surgery. These problems will persist as long as ear products are being used or until healing is complete. However, it is particularly prominent for the first several days after surgery. Complete loss of hearing is a rare problem that should be reported immediately to your surgeon.

Poor External Ear shape- Displacement of the out ear eyelid away from the face or head is a rare complication. Further surgery such as delayed otoplasty may be required at the time or after surgery to correct this condition or to correct asymmetry.

Scarring- All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the eyelid and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the eyelid or small skin cysts from sutures. In some cases scars may require surgical revision or treatment.

Damage to Deeper Structures- There is the potential for injury to deeper structures including, nerves, blood vessels, support structures, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of ear reconstruction procedure performed and the associated areas where donor tissue may need to be harvested. Injury to deeper structures may be temporary or permanent.

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Asymmetry- The human face is normally asymmetrical. There can be a variation from one side to the other in the results obtained from ear reconstructive surgery. Additional surgery may be necessary to attempt to revise asymmetry.

Pain- You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after blepharoplasty surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue.

Allergic Reactions- In rare cases, local allergies to tape, suture materials and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during surgery and prescription medications. Allergic reactions may require additional treatment.

Delayed Healing- Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin loss and wound healing complications.**

Long term effects – It is important to remember to avoid sun exposure for 6 months after skin procedures. Sun tanning can result in tissue loss and scarring even when a bathing suit covers the area. Scars tend to fade with time but will be significantly harmed by sun exposure. Sun exposure will also increase your risk of future skin lesions or cancers.

Need for revision – Certain ear operations are more likely to require revision surgery. In sensitive areas Dr. Lowe will often tell you to expect a number of reconstructive stages to optimize the results. This may involve scar revision, Dermabrasion, steroid injections, and laser treatments. Dr. Lowe may need to refer you to someone else if he does not have access to the appropriate treatment device.

Staged procedures – When the ear defect or deformity is significant a staged reconstruction may be necessary or required. Staged reconstruction means that patients will require more than one operation to obtain the best results. Often staged reconstruction involves moving tissue from one area to another and creating a new defect in the process. On occasion local tissue will be moved with an attachment that must be divided at a later date. Staged procedures require a period of recovery and healing between stages.

Location – Patients are expected to participate in their own clinical care. The exact location of skin cancers, lesions, or biopsy sites must be confirmed by patients and/or family members. Patients within our practice should not expect the surgeon, referring physician, or dermatologist to identify the location of disease solely on their own. Patients and/or family members will be required to describe and confirm the area of concern prior to surgical excision as part of the standard consent process.

Functional alterations – Changes may occur after ear reconstructive surgery that may limit a patient's function. Patients may recover at different rates following ear surgery, but the more surgery you have done the more difficult the recovery.

Change in Skin Sensation- It is common to experience diminished (or loss) of skin sensation in areas that have had surgery. Diminished (or complete loss of skin sensation) may not totally resolve after an eyelid reconstruction with or without blepharoplasty.

Skin Contour Irregularities- Contour irregularities and depressions may occur after ear reconstruction. Visible and palpable wrinkling of skin can occur. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility and may require additional surgery. This may improve with time, or it can be surgically corrected.

Skin Discoloration / Swelling- Some bruising and swelling normally occurs following ear reconstruction. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

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Skin Sensitivity- Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.

Sutures- Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation requiring removal.

Surgical Anesthesia- Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Shock- In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Seroma- Fluid accumulations infrequently occur in between the skin and the underlying tissues. Should this problem occur, it may require additional procedures for drainage of fluid.

Unsatisfactory Result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of eyelid surgery. This would include risks such as asymmetry, unsatisfactory surgical scar location, unacceptable visible deformities, loss of function, poor healing, wound disruption, and loss of sensation. It may be necessary to perform additional surgery to improve your results. Additional surgical procedures such as a otoplasty may be needed to correct sagging which contributes to asymmetry.

Cardiac and Pulmonary Complications- Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary and fat emboli can be life-threatening or fatal in some circumstances. Air travel, inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of blood clots or swollen legs that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Recurrent Cancer or Failure to Cure – In cases of ear lesions or cancer recurrence often relates to the type of disease, its location, and the treatment choice. If the surgeon removes a cancer the sample sent to pathology may later show an incomplete removal. A re-excision may be attempted or a different surgical approach taken. Sometimes the pathologist can misinterpret a margin or the type of cancer. Certain techniques increase the chances of complete removal a skin lesions such as frozen sections or Mohs surgery. Certain types of eyelid cancer that are removed may require other treatments such as radiation, node biopsy, or radical excisions. It is important that physicians involved in the patients care, the family, and patient are diligent in watching the area of concern.

Cancer Spread or Metastatic Disease - Although ear cancer spreading to distant sites is rare it is not impossible. Certain types of skin lesions or skin cancers have a greater risk of spread than others. The overall risk of skin cancer spread is as high as 10% in some studies. This depends on type of cancer, location, size, and individual factors. There are a variety of studies that can be performed to evaluate the risk of cancer spread, but these studies usually do not impact the long term outcome. It is important to remove skin cancers in a timely manner when possible and to report to your physician immediately any unusual lumps or bumps in the area of a previous skin lesion or cancer.

Frozen-Section Inaccuracy- Frozen-section techniques may be used to determine tissue pathology and completeness of tumor removal may be inaccurate. It is possible that subsequent tissue analysis may identify that there may be incomplete removal of the skin cancer or the presence of a different tissue

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pathology. Additional ear surgery may be necessary if it is determined that the removal of the ear cancer or lesion is incomplete.

ARE YOU HAVING MOHS SURGERY?

If you are undergoing Mohs surgery, the risk of the procedure should be explained by the physician performing the procedure. Mohs surgery is indicated in the treatment of certain types of eyelid cancer in sensitive areas only. It should be noted that when you are referred to the Mohs surgeon he or she will meet you and schedule the removal of the skin cancer. Education brochures on Mohs surgery are usually available in the office. If the Mohs surgeon thinks that he or she can close the defect and you agree, then that is fine with Dr. Lowe. It is important to understand that the defect may be greater than the patient or family anticipated. Dr. Lowe always tries to prepare for both the worse and best case scenario.

Typically, the Mohs surgery is performed the day before the reconstruction because it is difficult to know how long it will take to complete the cancer removal. The Mohs surgeon is responsible for arranging to have a trained and qualified surgeon close the defect. Dr. Lowe on occasion will agree to close the defect the next morning at his office or at the hospital under local anesthetic with sedation or general anesthesia. In such cases, Dr. Lowe will examine the defect the day of reconstruction and encourages the patient or family to look at the area prior to the reconstruction. A pre-operative work-up is usually required for all patients scheduled to have skin cancer surgery at a hospital.

ADDITIONAL ADVISORIES

Long-Term Results- Subsequent alterations in ear appearance may occur as the result of aging, weight loss or gain, sun exposure, pregnancy, menopause, or other circumstances not related to ear surgery. Ear surgery does not arrest the aging process or produce permanent support of the ear. Future surgery or other treatments may be necessary to maintain the results of ear surgery.

Skin Disorders / Skin Cancer- Ear reconstruction is a surgical procedure to restore skin and deeper structures of the ear. Skin disorders and skin cancer may persist and or recur independently of ear reconstructive surgery.

Female Patient Information- It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations after Surgery- Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray)-

Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

_____ I am a non-smoker and do not use nicotine products. I understand the risk of second-hand smoke exposure causing surgical complications.

_____ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

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It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

Mental Health Disorders and Elective Surgery- It is important that all patients seeking to undergo elective and non-elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

Medications- There are many adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions in addition to risk and potential surgical complications that may influence the long-term result of ear reconstructive surgery. Secondary surgery may be necessary to obtain optimal results. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with ear reconstructive surgery with or without otoplasty. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

If the ear deformity results in a significant loss of form or function, or interfere with your hearing, your health insurance company may cover ear reconstructive surgery and opposite ear surgery for symmetry. Most health insurance companies exclude coverage for cosmetic surgical operations such as otoplasty for big or prominent ears or any complications that might occur from cosmetic surgery. **Most insurance plans exclude coverage for secondary or revisionary surgery.** Please carefully review your health insurance subscriber information pamphlet.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery

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or hospital day-surgery charges involved with revision surgery will also be your responsibility. **In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

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CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ and such assistants as may be selected to perform the following procedure or treatment:

EAR RECONSTRUCTION SURGERY WITH OR WITHOUT OTOPLASTY (EAR ENHANCEMENT)

I have received the following information sheet:

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2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option.
12. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____